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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,346	03/26/2004	Yoshinobu Yamazaki	Q80493	7551

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,346	YAMAZAKI ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☒ Claim(s) 2-11 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 26 March 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-19 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment filed March 26, 2004 has been received and entered into the application. Accordingly, the specification at page 4 and claims 1, 9-12 and 16 have been amended.

Claim Objection

Claims 2-11 are objected to because in claims 2-11 the term "characterised" should preferably read as ---characterized--- and in claims 2-3, the term "stereocentre" should preferably read as ---stereocenter---. Appropriate correction is required.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

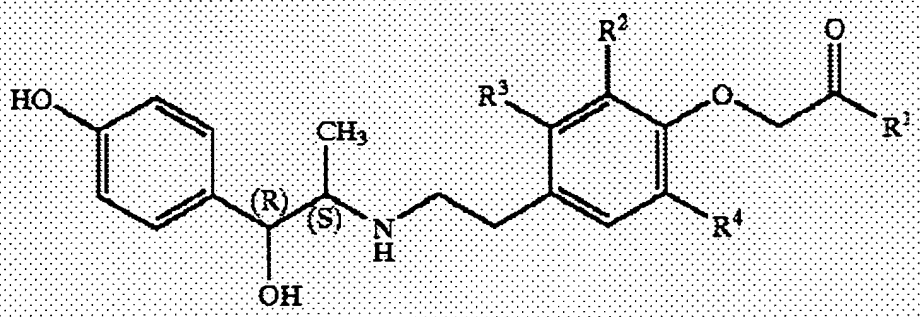
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al., (U.S. Patent No. 6,538,152) in view of Short et al., (U.S. Patent No. 6,720,014) and Guittard et al., (U.S. Patent No. 6,262,115).

Tanaka et al. teach a method for the treatment of urinary incontinence which comprises administering to a subject an effective amount of a phenoxyacetic acid compound encompassed by the present claims having the structure of the following formula (I):

(I)



wherein R^1 represents a hydroxy group, a lower alkoxy group, an aralkoxy group, an amino group, or a mono or di(lower alkyl)amino group; one of R^2 and R^3 is a hydrogen atom, a halogen atom, a lower alkyl group or a lower alkoxy group, while the other is a hydrogen atom; R^4 represents a halogen atom, a lower alkyl group, a halo (lower alkyl) group, a hydroxy group, a lower alkoxy group, an aralkoxy group, a cyano group, a nitro group, an amino group, a mono or di(lower alkyl)amino group, a carbamoyl group, a mono or di (lower alkyl)carbamoyl group or a group represented by the general formula:

—NHCOR^5

(wherein R^5 represents a hydrogen atom or a lower alkyl group); the carbon atom marked with (R) represents a carbon atom in R configuration; and the carbon atom marked with (S) represents a carbon atom in S configuration, or a pharmaceutically acceptable salt thereof.

(see the abstract and col. 2, lines 1-29). As the above mentioned pharmaceutically acceptable salts, such may be formed from various pharmaceutically acceptable mineral or organic acids as those of present claim 7. In particular, acids which are taught by Tanaka et al. include hydrochloric, hydrogen bromide, sulfuric, phosphoric, acetic, citric, tartaric, malic, succinic, fumaric, p-toluenesulphonic, benzenesulphonic, methanesulphonic, lactic and ascorbic, (see col. 16, lines 31-43).

The compound(s) may be administered by various routes and may be presented in various forms suitable for such routes. The routes include orally or parenterally and the dosage forms include powders, granules, fine granules, tablets, capsules, injections, solutions, ointments, suppositories, poultices and the like, (col. 17, lines 53-62).

The differences between the above and the claimed subject matter lie in that Tanaka et al. fail to teach:

(i) a "transdermal plaster"; and

(ii) the treatment of overactive bladder, either neurogenic or idiopathic.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because, as noted above, Tanaka et al. teach dosage forms such as ointments and poultices. In terms of their structure, it is not seen that a clear distinction can be made between these forms and the claimed "transdermal plaster" given the plain meaning of the terms.

Concerning the treatment of overactive bladder, it is believed that such would have been obvious because urinary incontinence is a symptom of overactive bladder, (see Short et al. in

Table 2 at cols. 65-66 under the entry for Ditropan® XL where "overactive bladder with symptoms of urge urinary incontinence, urgency and frequency" is set forth"). Thus, in a patient with overactive bladder which causes urinary incontinence, and in whom the urinary incontinence would have been treated in the manner taught by Tanaka et al., it would also have been considered a treatment for the causative condition, i.e., overactive bladder. An analogous situation would be where an antipyretic is administered to a patient suffering from a cold and who also has a fever. The antipyretic treatment could be reasonable referred to as a treatment for the cold.

As an alternative interpretation of the prior art and the claimed subject matter, the presently claimed treatment for overactive bladder would have been obvious because the art has recognized the overactive bladder and urinary incontinence as synonymous, (e.g., see Guittard et al. who teaches "Involuntary incontinence *also known as urge incontinence and overactive bladder...*", col. 1, lines 55-56). The Examiner believes that such is the case because of the plain meaning of the terms "over" and active" which connotes that the activity of the bladder is greater than normal, as would be the case in incontinence where urine is passed in an involuntary manner. It should be noted that while other references may be found where the two terms are distinguished, such would not diminish the propriety of the examiner's position because during the examination of the claims, terminology is to be interpreted in a broad and reasonable manner, (see MPEP § 2111). Clear, given the plain meaning of the terms "over" and "active", the above interpretation of the expression "overactive bladder" is clearly consistent with the direction provided for by the MPEP.

Finally, while Tanaka et al. fail to categorize the urinary condition as being either neurogenic or idiopathic, it is believed that one of ordinary skill in the art would have appreciated such concepts because the urinary condition is taught in general, thus indicating that sub-types thereof would be amenable to treatment. In this case, urinary incontinence either having a recognized, neurological etiology or an unknown etiology would be immediately envisaged.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/599,203, (Atty. Docket No. Q96974).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the phenoxyacetic acid compounds of the co-pending claims are

encompassed by the present claims and urinary frequency and/or incontinence of the co-pending claims are symptoms of overactive bladder, (e.g., see Short et al., U.S. Patent No. 6,720,014, cited by the Examiner, in Table 2 at cols. 65-66 under the entry for Ditropan® XL where "overactive bladder with symptoms of urge urinary incontinence, urgency and frequency" is set forth"). Given this, one of ordinary skill in the art would have been motivated to treat a patient within the scope of the present claims, i.e., a patient suffering from overactive bladder who is experiencing urinary frequency and/or incontinence, with the compounds of the co-pending claims, in order to ameliorate the patient's condition.

Also, while the present claims are silent with respect to the α1-adrenoreceptor blockers of the co-pending claims, such is not a patentable distinction because by containing the term "comprises", the present claims allow for additional, un-recited compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Accordingly, for the above reasons, the claims are deemed properly rejected.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

October 15, 2006